K010943

JUN 2 7 2001

3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Matthew M. Hull (610) 647-9700 ext. 7191
Name of the Device	Synthes Sternal Fixation System (SFS)
Regulation & Classification	888.3010 - Cerclage, Fixation , Metallic (JDQ) 888.3030 – Plate, Fixation, Bone, Non-Spinal, Metallic (HRS) 888.3040 – Screw, Fixation, Bone, Non-Spinal, Metallic (HWC)
Predicate Device	- Pectofix Dynamic Sternal Fixation System (K000694) - Pioneer Silcoat Sternal Cable (K993286)
Device Description	The Synthes SFS is a system consisting of machined Titanium plates and/or an intercostal hook connected with a quick-release pin. The plates utilize screw fixation to create the construct and some hook designs allow for supplemental screw fixation.
Intended Use	The Synthes (USA) Sternal Fixation System (SFS) is intended for use in primary or secondary closure/ repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.
Technological Characteristics	The Synthes SFS components will be made from Titanium in conformance with ASTM F-67, which is currently used in numerous standard bone plates and screws. The quick release pin used in the SFS plates will be made from Titanium Aluminum Niobium in conformance with ASTM F-1295. The technological innovation is to apply common plating system concepts to sternotomy applications while taking into consideration the critical requirement for possible post closure rapid re-entry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Mr. Matthew M. Hull
Senior Regulatory Specialist
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K010943
Trade/Device Name: Synthes Sternal Fixation System (SFS)
Regulation Number: 888.3010, 888.3030 and 888.3040
Regulatory Class: II
Product Codes: JDQ, HRS and HWC
Dated: March 30, 2001
Received: March 29, 2001

Dear Mr. Hull:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. Indications for Use Statement

510(k) Number (if known): K010943

Device Name: Synthes Sternal Fixation System

Indications/ Contraindications:

The Synthes (USA) Sternum Fixation System is intended for use in primary or secondary closure/ repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_
(Per 21 CFR 801.109)

B Mitchell TMD for CMW
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010943